Atty. Dkt. No.: 141202 (553-1449)

## Remarks

Claims 1-65 and 69 -76 and 86-102 were pending in the present application, of which claims 7-8, 15-24, 77-86 and 102 have been canceled without prejudice or disclaimer of the subject matter therein. New claims 103-110 have been added. It is respectfully submitted that the pending claims define allowable subject matter.

The Examiner is thanked for indicating claims 66-68 to be allowable.

Claims 1-6, 8, 10-11, 15-23, 29-31, 41, 45, 46, 48, 50, 54 & 65 are rejected under 35 USC § 103(a) as being unpatentable over Reilly (USP 2003/0004463) and further in view of Hamadeh (USP 2004/0088188). Claims 5 and 19 have been rejected under 35 USC § 103(a) as being unpatentable over Reilly '463 and further in view of Hamadeh '188 and further in view of Satyamurthy (Satyamurthy, N. et al. "Electric Generators for the Production of the Positron-Emitter Labeled Radiopharmaceuticals: Where Would PET Be Without Them?" Clinical Positron Imaging. Vol. 5, No. 5: 233-253, 1999). Claims 7, 21, 26, 27-29, 31, 42, 47 and 57 have been rejected under 35 USC § 103(a) as being unpatentable over Reilly '463 and further in view of Hamadeh '188 and further in view of Critchlow '930. Claim 30 has been rejected under 35 USC § 103(a) as being unpatentable over Reilly '463 and further in view of Hamadeh '188 in view of Critchlow '930 and further in view of Satyamurthy. Claims 9, 12-13, 35, 36, 38, 43, 49, 51, 54, 56, 58, 61-63, 65, 66-68, 70-77, 79 and 80 been rejected under 35 USC § 103(a) as being unpatentable over Reilly '463 and in view of Hamadeh '188 in further view of Tamaki (Tamaki et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp.1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989). Claims 32, 33, 37 and 57 have been rejected under 35 USC § 103(a) as being unpatentable over Reilly '463 and in view of Hamadeh '188 in view of Critchlow '930 and in further view of Tamaki '1989. Claims 14, 25, 39, 44, 52, 53, 59, 60, 64, 69 and 78 have been rejected under 35 USC § 103(a) as being unpatentable over Reilly '463 and in view of Hamadeh '188 in view of Tamaki and in further view of Kroll (USP

2005/0288869). Claims 34 and 86-102 have been rejected under 35 USC § 103(a) as being unpatentable over Reilly and in view of Hamadeh in view of Tamaki, in view of Critchlow and in further view of Kroll (USP 2005/0288869). Claims 81-83 under 35 USC § 103(a) as being unpatentable over Reilly '463 and further in view of Haines (6529692). Applicants respectfully traverse these rejections for reasons set forth hereafter.

Initially, the Examiner and the Supervising Examiner are thanked for holding a telephone conference with the undersigned on September 15, 2009. It is believed that the telephone conference significantly advanced the issues in the present application. The above claim amendments and new claims are submitted based upon the discussion during the interview.

The Examiner is thanked for indicating claim 66 to be allowable. Independent claims 35, 40, 45, 55, 61 and 65 have been amended to add the recitation of a plurality of delivery lines interconnected between a dispensing station and a plurality of PET imaging systems and to further recite that the control system controls dispensing of individual doses over the delivery lines. Based upon these claim amendments, as well as the arguments of record, it is submitted that claims 35-69 are allowable.

Independent claim 86 has been replaced with new independent claim 103. It is submitted that the prior art fails to teach or suggest a portable administration system as defined in claim 103. Claim 103 recites a portable system having a movable structure on wheels that holds a multi-dose container, a dispensing station, an ion chamber and a computer system. The dispensing station has a pump system and a liquid transfer path. The ion chamber has an ion chamber inlet and outlet. The liquid transfer path enters the ion chamber at the inlet and exits the ion chamber at the outlet. The pump system withdraws an individual dose from the multi-dose container and moves the individual dose through the ion chamber inlet to the ion chamber. The pump system moves the individual dose out of the ion chamber outlet for subsequent injection to a patient.

The prior art fails to teach or suggest the structure of claim 103. Reilly describes a radiation dose calibration unit 200 that includes a syringe 60. The syringe is pulled in one

Atty. Dkt. No.: 141202 (553-1449)

direction to draw liquid from the source 40 along a tube into the calibration unit 200. The syringe 60 then moves in the opposite direction to force the liquid back out of the calibration unit 200 over the same tube in which the liquid was drawn into the syringe. The configuration of Reilly would be unreliable and potentially inaccurate in that a portion of the liquid from source 40 could remain within the line between the valve 50 and the calibration unit 200. Hence, the calibration unit 200 would not receive the entire dose and could mis-read the radioactivity. Thus, Reilly's system which pulls liquid in and pushes liquid out of the calibration unit 200 over a common line bi-directionally, is less accurate and less desirable than the claimed configuration which conveys the dose through an inlet to an ion chamber and out a separate outlet of the chamber along a continuous path before injection to a patient.

Claim 26 is patentable over the prior art for reasons similar to those discussed above in connection with claim 103. Claim 26 recites an ion chamber that has an inlet and a separate outlet. The pump system moves the individual dose through the ion chamber inlet to the ion chamber where the radioactivity is measured. The pump system then discharges the dose through the ion chamber outlet along the liquid transfer path. Reilly does not teach or suggest any such configuration.

Claim 104 defines a portable system having, among other things, a multi-dose container, dispensing station and an ion chamber provided on a movable structure. A computer system on the movable structure is configured to calculate a target dosage for an individual dose based on at least one of a half-life of the pharmaceutical and a weight of the individual. The computer system controls the pump system to withdraw an amount from the multi-dose container based on this calculated target dosage. The withdrawn amount is moved to the ion chamber, the radioactivity is measured and the computer system compares the measurement with the target dosage to determine whether the withdrawn amount corresponds to the target dosage. The computer system then controls the pump system to discharge the measured amount from the ion chamber as an individual dose when the measurement from the ion chamber corresponds to the target dose.

The prior art fails to teach or suggest any such computer controlled dose management system.

Reilly's system is primarily described in the context of a <u>manually</u> controlled valve assembly and syringe. While Reilly refers to the potential automation or computer control of certain valves, nowhere does Reilly describe an automated system as claimed for dose calculation and control using an ion chamber. Reilly does not describe a computer system that calculates target dosages. Nor does Reilly teach or suggest to provide a computer system on a portable cart that controls the withdrawal of an amount from a multi-dose container based on ion chamber measurements and a computer calculated target dosage. Nor does Reilly teach or suggest to measure radioactivity of an amount drawn from the multi-dose container to determine whether the withdrawn amount corresponds to the radioactivity of a target dosage. Thus, claim 104 is patentable over the prior art.

Claim 70 is also patentable over the prior art for reasons discussed above in connection with claim 104. Claim 70 defines an imaging system having, among other things, a computer system that calculates target dosage and controls the withdrawal of an amount from a multi-dose container based on a target dosage. Claim 70 further provides that the computer system measures, through the ion chamber, the radioactivity of the withdrawn amount, performs a comparison to determine whether the withdrawn amount corresponds to the target dosage and then controls discharge of the amount based thereon. As noted above, Reilly fails to teach or suggest any such computer controlled operation.

By way of example only, the individual dose may be drawn into the ion chamber of claims 26, 70, 103 and 104 as a single amount of liquid or as two or more partial doses of liquid. For example, the individual dose may be formed from two half-doses that are both drawn into the ion chamber. The partial doses may be separated by saline where partial doses collectively correspond to a desired individual dose. By way of example, the claimed liquid transfer line may run continuously through the ion chamber or be separated such that a first tube dumps into a fluid holding container within the ion chamber and a second tube draws the liquid from the ion

**PATENT** 

Atty. Dkt. No.: 141202 (553-1449)

chamber after the radioactivity is measured. As a further example, the liquid transfer line may terminate at the ion chamber inlet and restart at the ion chamber outlet. The liquid transfer path may be formed of one or more tubes, lines, cavities, channels and the like.

In view of the foregoing comments, it is respectfully submitted that the prior art fails to teach or suggest the claimed invention. Should anything remain in order to place the present application in condition for allowance, the Examiner is kindly invited to contact the undersigned at the telephone number listed below.

Respectfully Submitted,

Dean Small, Reg. No.: 34,730

THE SMALL PATENT LAW GROUP

225 S. Meramec, Suite 725 St. Louis, Missouri 63105

(314) 584-4081